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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,300	06/25/2003	Danilo Porro	2027.594097/RFE (2005942)	8974
23720	7590	05/23/2006	EXAMINER	
WILLIAMS, MORGAN & AMERSON 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			SCHLAPKOHL, WALTER	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 05/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/606,300	<b>Applicant(s)</b> PORRO ET AL.	
	<b>Examiner</b> Walter Schlapkohl	<b>Art Unit</b> 1636	<i>WLF</i>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 12-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/21/06</u> | 6) <input type="checkbox"/> Other: _____  |

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#### **DETAILED ACTION**

Receipt is acknowledged of the papers filed 2/21/2006. Claims 12-14 are pending and under examination in the instant application.

#### ***Specification***

Applicant's amendment to the specification in the papers filed 2/21/06 is acknowledged.

The disclosure is objected to because of the following informalities: the continuing data mentioned in the first page of the specification should be updated to refer to the issued patent from US Patent Application 09/630,983.

Appropriate correction is required.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 2/21/06 has been considered by Examiner and a signed and initialed copy is being returned to Applicant as a part of the instant Office Action.

#### ***Claim Objections***

Claims 12-14 are objected to because of the following informalities: the claims lack proper status identifiers. On

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6/25/2003 Applicant submitted a preliminary amendment to the application in which claims 12-14 were amended. MPEP

714.II.C.A. states:

Claims added by a preliminary amendment must have the status identifier (new) instead of (original), even when the preliminary amendment is present on the filing date of the application and such claim is treated as part of the original disclosure. If applicant files a subsequent amendment, applicant must use the status identifier (previously presented) if the claims are not being amended, or (currently amended) if the claims are being amended, in the subsequent amendment. Claims that are canceled by a preliminary amendment that is present on the filing date of the application are required to be listed and must have the status identifier (canceled) in the preliminary amendment and in any subsequent amendment.

Therefore, Applicant's claims should be accompanied instead by the status identifier (previously presented).

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description

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requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record set for in the Office Action mailed 12/6/2005.**

*Response to Arguments*

Applicant argues that the methodology for determining compliance with the written description requirement as defined by MPEP 2163.II.Aff includes first, determination of what each claim as a whole covers; second, review of the entire application to understand how it provides support for the claimed invention and each element or step thereof; and third, determination of whether there is sufficient written description to inform the skilled artisan that Applicant was in possession of the claimed invention as a whole at the time the application was filed.

Applicant further argues that, "the claims in question are original claims (identical to those originally presented in the parent application) drawn to a genus." Applicant further argues that references such as Smirnoff et al (WO 99/33995; IDS Ref. B2) and Smirnoff (*Curr. Opin. Plant Biology*, June 2000; of

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record) would have been known to one of skill in the art at the time of filing of the parent application and that from such references, the functional term L-galactose dehydrogenase (LGDH) would have been clear to one of skill in the art.

Applicant further argues that adequate written description has been shown both by structural chemical formulae and sufficient, relevant, identifying characteristics.

Specifically, Applicant argues that phrases such as "at least about 90% similarity to SEQ ID NO:XX" or "at least about 90% identity to SEQ ID NO:XX" are exactly equivalent to a list of sequences (with the ordinary skilled artisan understanding an amino acid or nucleic acid sequence as a "structural chemical formula") different from SEQ ID NO:XX by 0 amino acids/nucleic acids, 1 amino acids/nucleic acids (of which there are  $n$  such sequences, wherein  $n$  is the length of the sequence of SEQ ID NO:XX), 2 amino acids/nucleic acids (of which there are  $n*(n-1)$  such sequences, wherein  $n$  is the length of the sequence of SEQ ID NO:XX), ...to about  $10\%*n$  amino acids/nucleic acids (of which there is a vast number of sequences for values of  $n$  common for the entire amino acid sequence of proteins). Therefore, Applicant argues, phrases such as "at least about 90% similarity to SEQ ID NO:XX" are vastly more concise while still providing equivalent information.

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Concerning a description of sufficient, relevant and identifying characteristics, Applicant argues that the present claims recite LGDHs, which the skilled artisan would understand to refer to enzymes having the functional characteristics of being NAD<sup>+</sup>-dependent proteins capable of catalyzing the conversion of L-galactose to L-galactono-1,4-lactone. Applicant further argues that these functional characteristics are coupled to a disclosed correlation between function and structure, namely, the levels of similarity or identity of SEQ ID NOs: 11 and 12 recited in the claims. Applicant notes that the claims do NOT recite every protein having at least about 90% similarity to or at least 90% identity to SEQ ID NO: 11, but rather *LGDHs* which have at least about 90% similarity/identity to SEQ ID NO: 11.

Applicant also argues that claims drawn to a genus require a written description of a "representative number of species" and that there is no *per se* ruling regarding how many species constitute a representative number. Along those lines, Applicant argues that written description of the invention need only be so specific as to lead one having ordinary skill in the art to the claimed genus. Applicant further argues that the instant disclosure presents two species: "an LGDH having 100% identity to SEQ ID NO:11 and a coding region having 100%

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identity to SEQ ID NO:12." Applicant seems to argue that these two species are a representative number of LGDH enzymes having at least about 90% similarity/identity to SEQ ID NO:11.

Applicant's arguments have been carefully considered and are respectfully found unpersuasive for the following reasons. First, whether or not the claims are drawn to a genus of a previously presented claim has no relevance to the written description rejection or the factors to be considered in the determination of such a rejection.

Second, Examiner agrees with Applicant that one of ordinary skill in the art at the time of filing would have understood an LGDH to be an enzyme responsible for the conversion of L-galactose to L-galactono-1,4-lactone in an  $\text{NAD}^+$ -dependent manner as taught by Smirnoff (ibid).

However, Applicant's arguments that adequate written description has been shown both by structural chemical formulae and sufficient, relevant, identifying characteristics is found unpersuasive for two main reasons. First, Applicant's claimed invention is a method for producing ascorbic acid comprising obtaining a recombinant yeast capable of converting an ascorbic acid precursor into ascorbic acid, wherein the yeast is transformed with a coding region encoding LGDH having at least about 90% similarity/identity with SEQ ID NO: 11 or wherein the



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coding region itself has at least about 90% identity to SEQ ID NO: 12 such that the recombinant yeast, when cultured in a medium comprising an ascorbic acid precursor produces ascorbic acid which is then isolated. Thus, while the list of those sequences with at least about 90% similarity or identity to the recited sequences may be clear to one of ordinary skill in the art, those sequences of at least about 90% similarity or identity to the recited sequences which can be transformed into a host yeast such that the yeast is capable of producing ascorbic acid when grown in a medium comprising an ascorbic acid precursor are not. In this regard, the disclosure of one *LGDH* amino acid sequence is not sufficient to identify other *LGDH* enzymes with even 95% sequence identity which, when transformed into a yeast, will result in a recombinant yeast capable of producing ascorbic acid. This is because, at the time of the effective filing date of the instant application, *LGDH* was a newly-discovered enzyme and, according to Smirnoff, "the only plant dehydrogenase acting on a non-phosphorylated sugar" (ibid). Thus, the art is silent with regard to relevant, identifying sequence characteristics of *LGDHs* and the instant disclosure provides only one example of an *LGDH* amino acid sequence which, when transformed into a yeast, results in a yeast capable of producing ascorbic acid. Given the lack of

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prior art on LGDH enzyme sequences, including functional motifs and other identifying characteristics, the disclosure of one representative LGDH amino acid sequence in the specification is not sufficient to lead one of ordinary skill in the art to the genus of LGDH enzymes with at least about 90% identity/similarity to SEQ ID NOs: 11 and 12 such that, when transformed into yeast, the resulting yeast is capable of generating ascorbic acid when cultured in a medium comprising an ascorbic acid precursor.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an

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invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 11-14 of copending Application No. 10/606,302. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. **This rejection is maintained for reasons of record set forth in the Office Action mailed 12/6/2005.**

Claims 12-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,630,330. **This is a new rejection not necessitated by Applicant's amendment.**

Although the conflicting claims are not identical, they are not patentably distinct from each other because in the case of instant claims 12-14, they are generic to all that is recited in the respective claims of the patent, i.e., the patented claims fall entirely within the scope of each of instant claims 12-14.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Smirnoff et al (WO 99/33995; IDS Ref. B2).

Smirnoff et al teach a method of generating ascorbic acid comprising obtaining a recombinant yeast capable of converting an ascorbic acid precursor into ascorbic acid, wherein the yeast is functionally transformed with a coding region encoding L-galactose dehydrogenase (LGDH) having at least about 90% similarity or identity with SEQ ID NO: 11 or having at least about 90% identity with coding sequence SEQ ID NO: 12, and further wherein the recombinant yeast is cultured and the ascorbic acid is isolated (see entire document, especially page 3, 2<sup>nd</sup> full paragraph; page 4, first four paragraphs; page 2, last full paragraph; page 16, 2<sup>nd</sup> full paragraph; and page 21, 1<sup>st</sup> and 2<sup>nd</sup> full paragraphs). Although Smirnoff et al do not

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explicitly teach LGDH of SEQ ID NO: 11 or a sequence encoding LGDH with at least about 90% identity to SEQ ID NO: 12, Smirnoff et al inherently teach this limitation since the pPB1121 and pGPTV-kan vectors recited on page 21, 2<sup>nd</sup> full paragraph, comprise such sequences.

### ***Claim Rejections - 35 USC § 103***

The rejection of claims 12-13 under 35 USC § 103 made in the previous Office Action is hereby withdrawn.

### ***Response to Arguments***

Applicant's arguments with respect to the rejection of claims 12-13 made under 35 USC § 103 have been carefully considered and found persuasive.

### **Conclusion**

Certain papers related to this application may be submitted to the Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is (571) 273-8300. Note: If Applicant does submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative.

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NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent applications to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at (800) 786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Walter Schlapkohl whose telephone number is (571) 272-4439. The examiner can normally be reached on Monday

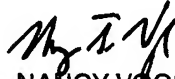
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through Thursday from 8:30 AM to 6:00 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.

Walter A. Schlapkohl, Ph.D.  
Patent Examiner  
Art Unit 1636

May 8, 2006

  
NANCY VOGEL  
PRIMARY EXAMINER